



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2011-0449; FRL-9346-4]

#### Acequinocyl; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of acequinocyl in or on multiple commodities which are identified and discussed later in this document. This regulation additionally removes several established individual tolerances, as they will be superseded by inclusion in crop subgroup tolerances or by updated commodity terminology. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0449. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in

hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: *nollen.laura@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at

*[http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).*

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0449 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your

non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0449, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Summary of Petitioned-For Tolerances**

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL-8880-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7864) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.599 be amended by establishing tolerances for residues of the miticide acequinocyl, [2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione] and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, expressed as acequinocyl equivalents, in or on bean, succulent shelled at 0.15 parts per million (ppm); caneberry subgroup 13-07A at 4.5 ppm; cherry at 0.8 ppm; cowpea, forage at 9.0 ppm; cucumber at 0.15 ppm; melon subgroup 9A at 0.06 ppm;

soybean, vegetable, succulent at 0.25 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 1.6 ppm; and berry, low growing, subgroup 13-07G at 0.4 ppm. The petition additionally requested that 40 CFR 180.599 be amended by removing the established tolerances for residues of acequinocyl in or on grape at 1.6 ppm and strawberry at 0.4 ppm, as they will be superseded by inclusion in subgroup 13–07F and 13–07G, respectively. That notice referenced a summary of the petition prepared on behalf of IR-4 by Arysta LifeScience North America LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels for several commodities. Additionally, the Agency has determined that tolerances should be established on the meat byproducts of livestock commodities and the previously established tolerances on the liver of livestock commodities should be removed. The Agency also determined that a tolerance is necessary on cowpea, hay. Finally, EPA determined that the proposed tolerance on cherry should be established as two tolerances on sweet and tart cherry. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for

which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for acequinocyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acequinocyl follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Acequinocyl exhibits low acute toxicity via the oral, dermal and inhalation routes of exposure, as well as in primary eye and primary skin irritation studies. It is not a dermal sensitizer. Acequinocyl is a known Vitamin K antagonist; therefore, it is thought to produce adverse effects by disrupting the blood coagulation system, as indicated by increased prothrombin time, increased activated partial thromboplastin time, and internal hemorrhages.

In rat studies, including a subchronic oral toxicity study, a 28-day dermal toxicity study, and a chronic feeding/oncogenicity study, acequinocyl increased prothrombin and activated partial thromboplastin. Internal hemorrhages were observed in both a rat and rabbit developmental toxicity study, a mouse subchronic/chronic toxicity study, and in a 2-generation reproduction rat study. In a combined chronic toxicity/oncogenicity study in rats, enlarged eyeballs were observed. Hepatotoxicity in the mouse was evidenced by histopathology and increased liver enzymes.

In both rat and rabbit developmental toxicity studies, acequinocyl increased the number of resorptions noted. Developmental effects (i.e., resorptions) occurred at a dose that was higher than or the same as the dose that caused maternal toxicity. In the 2-generation reproduction toxicity study in the rat, there was no evidence of reproductive toxicity, though there were notable toxic effects observed in offspring that were not observed in adults including swollen body parts, protruding eyes, clinical signs, delays in pupil development and increased mortality occurring mainly after weaning.

There was no evidence of carcinogenic potential in either the rat or mouse carcinogenicity studies. There was also no concern for mutagenic activity as indicated by several mutagenicity studies. Therefore, acequinocyl is classified as “not likely to be carcinogenic to humans.”

Specific information on the studies received and the nature of the adverse effects caused by acequinocyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “**Acequinocyl**; Human-Health Risk Assessment for Proposed Section 3 Uses on Succulent Soybean Vegetable; Succulent Shelled Beans;

Cowpea Forage; Caneberry Subgroup 13-07A; Melon Subgroup 9A; Cucumber, Cherry; Low-Growing Berry Subgroup 13-07G; and Small Fruit Vine Climbing, Except Fuzzy Kiwifruit, Subgroup 13-07F,” pp. 31-33 in docket ID number EPA-HQ-OPP-2011-0449.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for acequinocyl used for human risk assessment is shown in the Table of this unit.

**Table —Summary of Toxicological Doses and Endpoints for Acequinocyl for Use in Human Health Risk Assessment**



Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	N/A	N/A	An endpoint attributable to a single dose was not identified in the database.
Chronic dietary (All populations)	NOAEL = 2.7 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.027 mg/kg/day  cPAD = 0.027 mg/kg/day	Carcinogenicity study in mice (18 month); LOAEL = 7.0 mg/kg/day based on the clinical chemistry and microscopic non-neoplastic lesions (brown pigmented cells and perivascular inflammatory cells in liver).
Dermal, short-term (1 to 30 days)	Dermal study NOAEL = 200 mg/kg/day	LOC (occupational/residential) for MOE = 100	28-day dermal study in rats; LOAEL = 1,000 mg/kg/day based on increased clotting factor times.
Inhalation, short-term (1 to 30 days)	Oral NOAEL = 60 mg/kg/day (inhalation absorption rate = 100%) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x	LOC (occupational/residential) = MOE <100	Developmental toxicity study in rabbits; Maternal LOAEL = 120 mg/kg/day based on clinical signs (hematuria, reduced fecal output, body weight loss, and reduced food consumption) and gross necropsy findings (pale lungs and liver, hemorrhaging uterus, fluid in the cecum, fur in the stomach, blood stained vaginal opening, blood-stained urinary bladder contents/urine).
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans."		

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference

dose. MOE = margin of exposure. LOC = level of concern. mg/kg/day = milligram/kilogram/day.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acequinocyl, EPA considered exposure under the petitioned-for tolerances as well as all existing acequinocyl tolerances in 40 CFR 180.599. EPA assessed dietary exposures from acequinocyl in food as follows:

- i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for acequinocyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.
- ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA utilized tolerance level residues and 100 percent crop treated (PCT) information for all registered and proposed uses. The assessment also used Dietary Exposure Evaluation Model (DEEM-FCID™) ver. 7.81 default processing factors, with the exception of those for grape juice and raisins.
- iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that acequinocyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for acequinocyl. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acequinocyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acequinocyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of acequinocyl for chronic exposures for non-cancer assessments are estimated to be 6.69 parts per billion (ppb) for surface water and 0.0036 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 6.69 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Acequinocyl is currently registered for the following use by commercial applicators and homeowners that could result in residential exposure: Landscape ornamentals in residential and public areas. Residential handlers are expected to complete all tasks associated with the use of

acequinocyl including mixing and loading (if needed), and application of acequinocyl with either a low-pressure hand wand or with a hose-end sprayer. EPA assessed potential short-term dermal and inhalation exposures to residential handlers from these scenarios. Residential handler exposure scenarios are considered to be short-term only, due to the infrequent use patterns associated with homeowner products. Postapplication exposure was not anticipated for the registered residential uses; therefore, a quantitative postapplication assessment was not conducted. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found acequinocyl to share a common mechanism of toxicity with any other substances, and acequinocyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acequinocyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The acequinocyl toxicity database is adequate to evaluate potential increased susceptibility of infants and children, and includes developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in rats. In the rat prenatal developmental toxicity study, developmental toxicity was indicated by increased resorptions and fetal variations. The developmental toxicity study in rabbits identified an increased number of complete resorptions. In the rat 2-generation reproductive toxicity study, both the maternal and reproductive toxicity LOAELs were not observed; however, the LOAEL for parental males was 58.9/69.2 mg/kg/day, based on hemorrhagic effects. The offspring systemic LOAEL was also 58.9 mg/kg/day. Though the offspring LOAEL was similar to that of parental males, the study noted increased qualitative susceptibility of pups (swollen body parts, protruding eyes, clinical signs, delays in pupil development and increased mortality). These effects occurred mainly after weaning.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for acequinocyl is complete except for immunotoxicity and acute and subchronic neurotoxicity testing. Recent changes to 40 CFR part 158 imposed new data requirements for immunotoxicity testing (OPPTS Guideline 870.7800) and acute and subchronic neurotoxicity testing (OPPTS Guideline 870.6200) for pesticide registration. The toxicology database for acequinocyl does not show any evidence of treatment-related effects on the immune system, and the overall weight-of-evidence suggests that this chemical does not directly target the immune system. Therefore, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently in use for overall risk assessment, and additional UFs are not needed to account for a lack of this study.

Previously, EPA concluded that exposure to acequinocyl does not pose a neurotoxicity concern. Acequinocyl is a known Vitamin K antagonist; neurotoxic compounds of similar structure were not identified. While there is potential evidence of neurotoxicity or neuropathology in the 2-generation reproduction study as well as the rat subchronic oral toxicity study, these toxicities are not considered to be primary effects because they were observed at very high doses and in the presence of more severe systemic effects in both studies. The Agency does not believe that conducting the acute and subchronic neurotoxicity studies will result in a lower POD than that currently used for overall risk assessment; therefore, additional UFs to account for neurotoxicity are not necessary.

ii. There is no evidence of increased susceptibility of rat or rabbit fetuses to *in*

*utero* exposure to acequinocyl. In the 2-generation reproduction study in rats, increased qualitative susceptibility was observed in offspring. However, EPA determined that the degree of concern is low for the noted effects because the effects were observed at the same doses as parental effects, and there is a clear NOAEL established which was used in endpoint selection.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acequinocyl in drinking water. Residential uses are not expected to result in postapplication exposure to infants and children. These assessments will not underestimate the exposure and risks posed by acequinocyl.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect

resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, acequinocyl is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acequinocyl from food and water will utilize 55 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of acequinocyl is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Acequinocyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to acequinocyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,500 for the general U.S. population, and 2,600 for females 13-49 years old. Because EPA's level of concern for acequinocyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, acequinocyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on



intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for acequinocyl.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, acequinocyl is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to acequinocyl residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Morse Methods (Meth-135 and #Meth-133, revision #3), two high-performance liquid chromatography methods with tandem mass-spectroscopy detection (HPLC/MS/MS), are adequate enforcement methodologies available to enforce the tolerance expression.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and

agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for acequinocyl.

### *C. Revisions to Petitioned-For Tolerances*

Based on analysis of the residue field trial data supporting the petitions, EPA revised the proposed tolerances on berry, low growing, subgroup 13-07G from 0.4 ppm to 0.50 ppm; bean, succulent shelled from 0.15 ppm to 0.30 ppm; cowpea, forage from 9.0 ppm to 6.0 ppm; caneberry subgroup 13-07A from 4.5 ppm to 4.0 ppm; and melon subgroup 9A from 0.06 ppm to 0.15 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures. EPA also determined that the proposed tolerance on cherry at 0.8 ppm should be established as two separate tolerances on cherry, tart at 1.0 ppm; and cherry, sweet at 0.50 ppm because residues were generally higher in tart cherries than in sweet cherries. EPA determined that a tolerance is necessary on cowpea, hay at 18 ppm. Based on the results of the data supporting the cowpea tolerance, the appropriate tolerance for residues of acequinocyl in or on cowpea, forage is 6.0 ppm. Typically, forage is harvested before the plant has bloomed. Because it

was not specified at what plant stage the product can be applied, EPA deemed it necessary to establish a tolerance on cowpea, hay as well. There is typically a 3-fold drying factor between forage and hay; therefore, EPA is establishing a tolerance for residues of acequinocyl in or on cowpea, hay at 18 ppm.

Finally, because cowpea forage and hay are significant feedstuff commodities for livestock, the maximum reasonable dietary burdens of acequinocyl were recalculated for acequinocyl using the Agency's most recent guidance on constructing reasonably balanced livestock diets. The Agency determined that the currently established tolerance level of 0.02 ppm for residues of acequinocyl in the fat of cattle, goat, horse, and sheep are still appropriate. Furthermore, the established 0.02 ppm tolerance level in the liver of cattle, goat, horse, and sheep is appropriate. However, EPA is revising the commodity definition to meat byproducts rather than liver in order to reflect the correct terminology. Therefore, EPA determined that tolerances should be established at 0.02 ppm for the meat byproducts of cattle, goat, horse, and sheep; and the established tolerances in the liver of cattle, goat, horse, and sheep should be removed.

## **V. Conclusion**

Therefore, tolerances are established for residues of acequinocyl, including its metabolites and degradates, in or on the commodities in the table in paragraph (a) of § 180.599. Compliance with the tolerance levels specified in the table of paragraph (a) of § 180.599 is to be determined by measuring only the sum of acequinocyl [2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione] and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, calculated as the stoichiometric equivalent of acequinocyl, in or on soybean, vegetable, succulent at 0.25 ppm; berry, low growing, subgroup 13-07G at 0.50

ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 1.6 ppm; bean, succulent shelled at 0.30 ppm; cowpea, forage at 6.0 ppm; cowpea, hay at 18 ppm; caneberry subgroup 13-07A at 4.0 ppm; melon subgroup 9A at 0.15 ppm; cucumber at 0.15 ppm; cherry, tart at 1.0 ppm; cherry, sweet at 0.50; cattle, meat byproducts at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat byproducts at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm. This regulation additionally removes established tolerances in or on grape at 1.6 ppm; strawberry at 0.40 ppm; cattle, liver at 0.02 ppm; goat, liver at 0.02 ppm; horse, liver at 0.02 ppm; and sheep, liver at 0.02 ppm.

## **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 20, 2012.

Daniel J. Rosenblatt,  
*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.599, paragraph (a), the table is amended by removing the entries for “Cattle, liver”; “Goat, liver”; “Grape”; “Horse, liver”; “Sheep, liver”; and “Strawberry” and by alphabetically adding the following commodities to read as follows:

**§ 180.599 Acequinocyl; tolerances for residues.**

(a) *General.* \* \* \*

Commodity	Parts per million
* * *	* * *
Bean, succulent shelled	0.30
Berry, low growing, subgroup 13-07G	0.50
Caneberry subgroup 13-07A	4.0
* * *	* * *
Cattle, meat byproducts	0.02
Cherry, sweet	0.50
Cherry, tart	1.0
* * *	* * *
Cowpea, forage	6.0
Cowpea, hay	18
Cucumber	0.15
* * *	* * *
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	1.6
* * *	* * *
Goat, meat byproducts	0.02
* * *	* * *
Horse, meat byproducts	0.02
Melon subgroup 9A	0.15
* * *	* * *
Sheep, meat byproducts	0.02
Soybean, vegetable, succulent	0.25
* * *	* * *

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